

REMARKS

The following are comments applicants have on the Examiner's March 9, 2005 Action.

Status of the Claims

The Examiner's Action addressed Claims 1, 7 to 11, 14, 15, 18, and 19. Claim 8 to 10 have been cancelled without prejudice. Claims 1, 11, 14, 15, and 18 have been amended. Claims 20 to 32 have been added. The claims presently pending are Claims 1, 7, 11, 14, 15, 18, and 19 to 32.

Discussion of the Amendments

Independent Claims 1 and 18 have been amended to specify that the reagent used to modify the DNA-containing complex is selected from the group consisting of citraconic anhydride and N-hydroxysuccinimide acetate. Support for this amendment is found in Claim 8, now cancelled.

In addition, Claims 1 and 18 have been amended to clarify applicants' invention as being respectively that of: (A) a process for modifying a colloid comprising a complex of DNA and cationic lipids or polymers in which the aforementioned reagent is reacted with cationic lipids or polymers of the complex to reduce, remove or reverse the charge of the surface thereof; and (B) a colloid comprising a complex of DNA and cationic lipids or polymers in which one or more of the cationic lipids or polymers have been modified by reaction with a reagent.

Amendments have been made to Claims 11, 14, and 15 for the purpose of making them consistent with the language of Claim 1 from which they depend.

Amendments of an editorial nature have been made to Claim 11.

Support for Claims 20 to 27 is found in Claims 7, 11, 14, 15, 18, and 19.

Support for Claims 28, 29, and 31 is found in the application at the paragraph bridging pages 3 and 4. Support for Claims 30 and 32 is found in the application at the second full paragraph on page 4.

No new matter has been added.

Traversal of the Examiner's Section 102 Rejection Based on Monahan et al.

The Examiner rejected independent Claim 1, and Claims 7, 9 to 11, 14, and 15 which depend from Claim 1, and independent Claim 18, and Claim 19 which depends from Claim 18, as being anticipated under Section 102(e) by U.S. Patent No. 6,379,966 to Monahan et al. Applicants traverse this rejection.

These claims distinguish over Monahan et al. in that they recite a colloid (or method for making or using the same) which comprises a DNA-containing complex in which citraconic anhydride (CCA) or N-hydroxy succinimide (NHS) acetate has been reacted with the cationic lipids or polymers of the complex (examples of such reactions are shown in Figures 4 and 7 of the application). By contrast, Monahan et al. does not disclose the reaction of anything with the cationic lipids of the DNA-containing complex described therein. Rather, Monahan et al. describes the electrostatic interaction of anionic polymers with the cationic lipids in a "recharging" process (see column 11, lines 39 to 44, and column 23, lines 56 to 65 thereof). While Monahan et al. does disclose the use of CCA and NHS ester, these compounds are disclosed therein solely for their use in forming the above-referenced anionic polymers and not for reacting with the cationic lipids. NHS ester is used as an agent which forms cross-links between anionic monomers and disulfide-containing monomers to

form a disulfide-containing anionic polymer. CCA is used to react with cationic polymers (polyvinylphenol, poly-L-tyrosine, and poly-L-lysine) to form anionic polymers.

Given the above, Monahan et al. does not anticipate applicants' claims and the Examiner's Section 102 rejection of Claims 1, 7, 9 to 11, 14, 15, 18, and 19 based on Monahan et al. should be withdrawn.

Traversal of the Examiner's Section 103 Rejection Based on Monahan et al.

The Examiner has rejected independent Claim 1, and Claims 7, 9 to 11, 14, and 15 which depend from Claim 1, and independent Claim 18, and Claim 19 which depends from Claim 18, as being rendered obvious under Section 103(a) by U.S. Patent No. 6,379,966 to Monahan et al. Applicants traverse this rejection.

In order to establish a *prima facie* case of obviousness, the Examiner must show that the cited art teaches or suggests each of the elements of the claimed invention. The Examiner has based his obviousness rejection upon the mistaken belief that Monahan et al. discloses the use of NHS esters and CCA as reagents which react with the cationic lipids or polymers of a DNA-containing complex. As stated above, Monahan et al. does not contain such a disclosure. As such, the Examiner has failed to establish a *prima facie* case of obviousness.

Given the above, Monahan et al. does not render applicants' claims obvious and the Examiner's Section 103 rejection of Claims 1, 7, 9 to 11, 14, 15, 18, and 19 based on Monahan et al. should be withdrawn.

Discussion of the Examiner's Section 102 Rejection Based on Semple et al.

The Examiner has rejected Claim 1 as being anticipated under Section 102(e) by U.S. Patent No. 6,287,591 to Semple et al. This rejection has been overcome by the above amendment.

Claim 1, as amended, distinguishes over the disclosure of Semple et al. in that it defines a method in which CCA or NHS acetate is reacted with a cationic lipid or a cationic polymer. Semple et al. does not recite the use of CCA or NHS acetate.

Given the above, Semple et al. does not anticipate Claim 1 and the Examiner's Section 102 rejection thereof based on Semple et al. should be withdrawn.

Traversal of the Examiner's  
Section 103 Rejection Based on Semple et al., Monahan et al., and Trubetskoy et al.

The Examiner rejected independent Claim 1, and Claims 7, 9 to 11, 14, and 15 which depend from Claim 1, and independent Claim 18, and Claim 19 which depends from Claim 18, as being rendered obvious under Section 103(a) by Semple et al. in view of Monahan et al. and the disclosure of U.S. Application Publication No. 2003/0026841 to Trubetskoy et al. which claims priority to a provisional application filed on December 31, 1999. Applicants traverse this rejection.

In order to establish a *prima facie* case of obviousness, the Examiner must show that one skilled in the art would have been motivated to modify or combine the disclosures of the cited references to arrive at the claimed invention. According to the Examiner, one skilled in the art would have been motivated to render neutral or anionic the surface potential of the DNA-containing complexes of Semple et al. using NHS ester or CCA, as taught in Monahan et al., because Semple et al. and Trubetskoy et al. teach that rendering the surface potential of a DNA-containing complex neutral

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or anionic allows for it to better resist degradation *in vivo*. The Examiner's rationale, however, is based on the incorrect belief that Monahan et al. discloses using NHS ester and CCA as reagents to modify the surface potential of DNA-containing complexes. As stated above, Monahahn et al. does not contain such a disclosure and neither do the other cited references. One skilled in the art would not, therefore, have been motivated to use NHS ester or CCA to modify the surface potential of the DNA-containing complexes of Semple et al.

Given the above, Semple et al., Monahan et al., and Trubetskoy et al. do not render applicants' claims obvious and the Examiner's Section 103 rejection of Claims 1, 7, 9 to 11, 14, 15, 18, and 19 based thereon should be withdrawn.

### Conclusion

In view of the above amendment and remarks, an early and favorable Action is requested respectfully.

Respectfully submitted,

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